IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

CHARLES GRAHAM, et al.,)
Plaintiffs,)) No. 3:16-cy-01954
v.) CHIEF JUDGE CRENSHAW
TONY C. PARKER, et al.,	
Defendants.)

STIPULATIONS OF FACTS AND OTHER MATTERS

Pursuant to Fed. R. Civ. P. 16 and the orders of this Court, the parties to this cause, through their counsel, respectfully stipulate as follows:

A. STIPULATIONS OF FACT

The parties agree that the following facts are uncontested and should be made a part of the evidentiary record at trial:

- 1. HCV is a contagious virus spread through contact with blood and bodily fluids that contain the Hepatitis C virus from a person already infected. The virus travels to, and infects, the liver, creating an inflammatory process referred to as "hepatitis."
- 2. For the first approximately six months following initial infection with the virus, persons with HCV are said to be in the "acute" phase of infection.
- 3. The body will spontaneously clear or resolve an acute hepatitis C infection in approximately 15-25% of cases.
- 4. In a majority of infected patients, hepatitis C infections do not spontaneously resolve, but result in chronic HCV infection.

- 5. A 5-point classification system is used for the degree of fibrosis (progressive scarring in the liver), ranging from F0 (no fibrosis) to F4 (cirrhosis).
- 6. The rate of progression in those who develop cirrhosis is not the same in all patients.
- 7. Cirrhosis is the late stage of liver scarring. There are two types of cirrhosis: compensated cirrhosis, which is asymptomatic, and decompensated cirrhosis, which is symptomatic. Individuals with cirrhosis are at risk of developing primary liver cancer, called hepatocellular cancer. The occurrence of either decompensated cirrhosis or hepatocellular carcinoma is referred to as "end-stage liver disease" (ESLD).
- 8. In the past, standard treatment for infections involved injections of a drug called interferon, which activates the immune system. However, that treatment process was long, resulted in a low rate of SVRs, and caused intolerable side effects.
- 9. In 2011, the Federal Drug Administration ("FDA") approved direct-acting antiviral drugs ("DAAs") to treat HCV.
- 10. Defendant Kenneth Williams, M.D., Ph.D., is Director of Medical Services, Chief Medical Officer, and Director of Pharmacy at the Tennessee Department of Correction.
- 11. Dr. Williams' responsibilities include developing and updating policies and practices that are directly responsible for oversight of inmate health care (for all diseases, not just hepatitis C). He is also responsible for clinical management of the contract with TDOC's medical vendor, Centurion of Tennessee, the medical aspects of the operation of CoreCivic of Tennessee, as well as the clinical management of the contract with TDOC's pharmacy vendor, Clinical Solutions Pharmacy.

- 12. Defendant Tony C. Parker is the Commissioner of the Tennessee Department of Correction.
- 13. Dr. Williams produced the Tennessee Department of Correction Chronic HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C in 2016.
- 14. Dr. Williams produced the guidance entitled "Evaluation and Management of Chronic Hepatitis C. Virus (HCV) Infection (Tennessee Department of Correction Clinical Guidance) in May 2019. This is the Department's most recent HCV Guidance, replacing the January 2016 guidance.
- 15. The 2019 HCV Guidance applies to healthcare professionals who treat prisoners held in Tennessee Department of Correction operated or privately contracted state prisons and TACHH.
- 16. The 2019 HCV Guidance provides controlling guidance for the evaluation, staging, tracking, and other treatment of patients with chronic HCV.
- 17. The Tennessee Department of Correction Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment ("TACHH") makes treatment determinations for inmates infected with HCV based upon their medical presentations.
- 18. TACHH members currently include Dr. Williams, Dr. Keith Ivens, Medical Director for CoreCivic, TDOC's private prison contractor, a representative of Centurion of Tennessee, and other medical professionals.
- 19. TDOC has acquired and operates two elastography devices (FibroScan), diagnostic tools for non-invasive measurement of the presence and extent of liver fibrosis.

20. While the exact number fluctuates, there are approximately 21,000 inmates

in TDOC custody.

21. There are approximately 4,740 persons in TDOC custody who are known

to be infected with HCV.

B. ADDITIONAL STIPULATIONS

The parties agree that to the following additional stipulations:

1. Expert witnesses for the parties may attend all court proceedings.

2. The Defendants may be excused from attendance at trial except as needed

for trial testimony on the condition that they may be called for rebuttal testimony on

reasonable notice.

3. The parties agree and move this Court to Order that, for good cause, any

HIPPA-protected medical information or confidential pharmaceutical prices information,

pursuant to Tenn. Code Ann § 10-7-504(n), which are subject to the Protective Orders in

this case and which are introduced at trial, shall be so designated and appropriately redacted

and/or filed under seal.

Dated: June 26, 2019

Respectfully submitted,

/s/ Thomas H. Castelli_

Thomas H. Castelli (BPR# 24849)

AMERICAN CIVIL LIBERTIES UNION

FOUNDATION OF TENNESSEE

P.O. Box 120160

Nashville, TN 37212

Tel.: (615) 320-7142

Fax: (615) 691-7219

tcastelli@aclu-tn.org

James G. Stranch, III (BPR 2542)

Karla M. Campbell (BPR 27132)

Callie K. Jennings (BPR 35198)

Anthony Orlandi (BPR 33988)

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BRANSTETTER, STRANCH & JENNINGS, PLLC

The Freedom Center
223 Rosa L. Parks Avenue, Suite 200
Nashville, TN 37203
Phone: (615) 254-8801
Fax: (615) 255-5419
jims@bsjfirm.com
karlac@bsjfirm.com
calliej@bsjfirm.com
aorlandi@bsjfirm.com

Stacie L. Price (BPR 03065) Sherry A. Wilds (BPR 021756) DISABILITY RIGHTS TENNESSEE 2 International Plaza, Suite 825 Nashville, Tennessee 37217 Phone: (615) 298-1080 staciep@disabilityrightstn.org sherryw@disabilityrightstn.org

On Behalf of Plaintiffs

HERBERT H. SLATERY III Attorney General and Reporter

/s/ James R. Newsom III
James R. Newsom III (BPR# 6683)
Special Counsel
Matthew R. Dowty (BPR 32078)
Office of the Tennessee Attorney General
40 South Main Street, Suite 1014
Memphis, TN 38103-1877
Tel. (901) 543-2473
Jim.Newsom@ag.tn.gov
Matthew.Dowty@ag.tn.gov

Steven A. Hart (BPR No. 7050) Pamela S. Lorch (BPR No. 8968) Office of the Attorney General and Reporter Post Office Box 20207 Nashville, TN 37202-0207 Steve.Hart@ag.tn.gov

On Behalf of Defendants

CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of June, 2019 a copy of the foregoing document was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the electronic filing system:

Thomas H. Castelli tcastelli@aclu-tn.org

Sherry A. Wilds Sherryw@disabilityrightstn.org

Karla M. Campbell karlac@bgsjfirm.com

Anthony A. Orlandi aorlandi@bsjfirm.com

Callie Kate Barker Jennings calliej@bsjfirm.com

Stacie L. Price staciep@disabilityrightstn.org

James Gerard Stranch, III gerards@bsjfirm.com

Pamela S. Lorch
Pam.Lorch@ag.tn.gov

James R. Newsom III Jim.Newsom@ag.tn.gov

Matthew R. Dowty

Matthew.Dowty@ag.tn.gov

/s/ Thomas H. Castelli
Thomas H. Castelli